### Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Special Nutritionals

ARMS#

13370



2 - LABEL SAMPLE

## Food and Drug Administration Office of Regulatory Affairs Collection Report

For Sample Number: 32555

Complaint Sample Sample collected per MedWatch #13370 assign **Episode Number** Origin Basis Sample Type Domestic

Surveillance Investigational

Flag Remarks

**FIS Smpl Num** 99920648 **PAC** 

03F800

Status In Progress Hours

FEI 1000117125

Flag

**Date Collected** 24-MAR-99

**Product Code** 54YEY99 Sampling District

DET-DO

Responsible Firm Manufacturer **NDC** Number

Permit Number Storage Rormnt.

Dealer is Consumer Crx/DEA Schedule Recall Num Yes

INV

Consumer Compl. Num Brand Name **DET-0833** Metacuts

Ambient

**Product Description** 

Beige capsules with grainy substance inside

Related Smpl Num Position Class

**Product Label** See continuation

Reason for Collection Complaint/Injury F/U (DET-0833) which generated MedWatch

MFG Codes WN2658A

**Expiration Date** 

0901

#13370. CFSAN facimile from HFS-636, dated March 12, 1999

Firm Legal Name Metaform

Address 22647 Ventura Blvd. #346 Woodland Hills, CA 91346 US

Type of Firm Shipper

Firm FEI **FCE** 3002654293

Weider Nutrition International

2002 South 5070 West Salt Lake City, UT

Manufacturer

1000117125

84104 US

Size of Lot I bottle containing 10 capsules

Est. Value Rcpt Type \$20 FDA484

Date Shipped & Doc. Ref.

Description of Sample

See continuation.

Method of Collection

l glass bottle containing 10 capsules collected from consumer

How Prepared See continuation

Collector's Identification on Package and/or Label "32555 3/24/99 ARP"

Collector's Identification on Seal "32555 4/1/99 Anthony R Petriella"

Sample Delivered To

DET-DO Sample Custodian

**Date Delivered** 

Orig C/R & Records To

**DEN-DO** 

Lab w/Split Sample

Document Number	<b>Document Date</b>	Document Type	Document Remarks
13370	03/12/1999	Other	CFSAN facsimile request for follow-up #1337 Attachment A1/A3
DET-0833	02/22/1999 03/25/1999	Other Affidavit	Complaint/Injury follow-up: Attachment B Affidavit signed by Mr. Attachment C1,C2
FDA-484	03/24/1999	Other Other	Photocopy of product label: Attachment D Carbon copy of product Receipt for Sample: Attachment E
			000002

Date: 04/27/1999 Page: 1 of 3

> Complaint/Injury F/U DET-0833 3/24,25,30/99

Food and Drug Administration Office of Regulatory Affairs Collection Report

For Sample Number: 32555

FDA-415a

03/24/1999

Other

Original official scal. Attachment F

Remarks

See continuation.

Payment Amount

Name of Signer

\$0.00

**Payment Method** 

No Charge

704(d) Sample Yes

702(b) Portion No

Collector's Name Anthony R Petriella

Date & Time of Signature

Meaning

ΕT

7,

Date: 04/27/1999 Page: 2 of 3

# Food and Drug Administration Office of Regulatory Affairs Collection Report

For Sample Number: 32555



#### Continuation:

#### **Product Label**

Metaform Metacuts dietary supplements packaged in a brown glass bottle labeled, in part "\*\*\*METAFORM\*\*\*PRE-EXERCISE AND ENERGY BOOSTER\*\*\*METACUTS\*\*\*60 CAPSULES\*\*\*WN2658A EXP0901\*\*\*

#### **Description of Sample**

10 beige capsules with grainy material inside. Capsule container is constructed of brown glass with a black screw cap top. Product label is brown, white and gold with white, black, gold and red lettering.

#### **How Prepared**

Date: 04/27/1999

Sample identified as "32555 3/24/99 ARP". Sample placed in brown paper bag identified "32555 3/24/99 ARP" and sealed as "32555 4/1/99 Anthony R. Petriella"

#### Remarks

Spl was temp sealed on day of collection (3/24/99) and stored in locked cabinet until next of	day On 3/25/99 spl then transferred
to locked spl room until 4/1/99. On 4/1/99, spl orig. scal broken for purposes of product lal	nel descr. Spl. was then again
immediately off sealed. Spl collected from consumer, Mr	ber deser opr was then again
Send results there	
Total tilling	

Page: 3 of 3 Complaint/Injury F/U DET-0833 3/24,25,30/99 ARP

The of the art, preworkout formula II-CUTSTM Thermogenic Blend ...scmers; methylxcanthines, ratoids. When these compounds are liet and exercise program, they rergy expenditure and work output.

at been evaluated by the ation. This product is not at, cure or prevent ony disease.

ecommended dosage. Taking more age will not be more effective and a offects, including heart attack. Do not use if you are pregnant or blood pressure, glaucoma, strake, isease, or any psychiatric disorder, drugs for depression, psychiatric or usen's disease, methyldopa, or any 10, pseudoephedrine ar edients found in cough/cold, loss products), or if you are prone ifficulty in urination due to preside with air professional prior to without a professional prior to without and contact a mely if dizziness, severe headache, ain, rapid and/or irregular

ons under the age of 18. DREN, ;, WITH LID TIGHTLY CLOSED WE SERVING A DAY

es in behavior, or noused occurs.





# METAFORM

PRE-EXERCISE AND ENERGY BOOSTER

DIETARY SUPPLEMENT

60 CAPSULES



ND

ER

Directions: Take four (4) capsules 30 to 60 minutes prior to workout.

# Supplement Facts Serving Size: Four (4) Capsules Servings Per Container: 15

Amount Per Serving	% Delly Value				
Chromium (as picolinate)	200 m	a)	170%		
Magnesium (as codde)	100 m	g	25%		
Postassium (as citrate)	100 m	g	4%		
Guarana ( <i>Paullinia cupana</i> ) (150 mg caffeine from 15% standardized extract)	1000 m (seed)	g	•		
Citrimax <sup>TM</sup> (min. ~50% (~)HCA)  "Garcinia cambogla" (ffuit)	1000 m	Q	•		
Ma Huang (Ephedra smica) (16 5 mg ephedrine from standardized extract) (whole herb)	275 rr	g			
L-Camitine tartrate	100 m	19	•		
Quercetin	100 m	ıg			
*Daily Value not established					
Other Ingredients: Magnesium silicate and	magnesit	ım s	tearate	<b>8</b> A	01
DISTRIBUTED BY: METAFORM®					6
22647 Ventura Blvd. #3	46				õ
Woodland Hills, CA, USA 9 1-800-439-8048 www.realmuscle.com/meta	1346			N2	Xp
ABETICS/1979GLYCEUCS: Use only under a physi	ician's su	PER	ision.	2	u
Citations - TM in a sendament of Intark	eath Con				

CUBETIC/1970GLYCHIC: Use only under a physician's supervision. Citrimax™ is a trademark of InterHealth Corp.

METACUTSTM is an ail read state and energy enhancer." METAC contains several ephedrine is bioflavonoids, and other alkalo combined, with a sensible diere encourage a rise in daily energi

'These statements have no Food and Drug Administrative intended to diagnose, tree

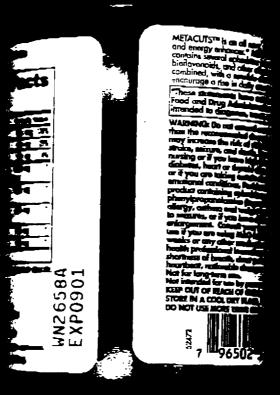
WARNING: Do not exa than the recommended do may increase the risk of stroke, seizure, and dept strate, segure, one cash nursing or if you have his disbette, heart or thyroid or if you are taking certs emotional conditions, Por эпу ргоралова phenylpropurotamme (\*\* \*\* allergy, asthma and west are used if you are using MAO and wests or any other medicalle health professional immediate shortness of breath, chest polynomia. sartbeat, noticeable cha Not for long-term use. Not intended for use by

KEEP OUT OF BEACH OF STORE IN A COOL DRY PLACE DO NOT USE MORE THAN

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Best Quality FDA







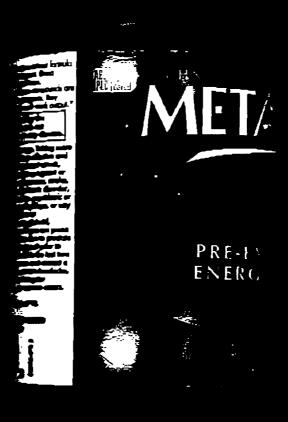


LERCINES

RE-EXERCISE AND NERGY BOOSTER



Best Quality FDA



32555 3/24/99 ABB uies 30 to 60 minutes METACUTST's is on all now, side of the ort, prewarkout formula and energy enhancer. \* METACUTST's Thermogenic Blend participate speed, and energy enhances to the source of the source o ent Facts % Delty Velue 100 mg 100 mg 1000 mg 1000 mg 275 mg 100 mg 100 mg featin Corp.



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32555

3/24/99

WN26584 EXP0901

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BL. CA, USA VITAG
D-10-1049
sch.com/mutatum

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METAFORA

PRF-ENERGISE AND ENERGY BOOSIER

COTABLE PARENT BU CAPSULES



Best Quality FDA

Supplement Facts

Supplement Facts

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